

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MERLE KOVTUN, et al.,

Plaintiffs,

No. C 10-4957 PJH

v.

**ORDER GRANTING MOTION
TO DISMISS**

VIVUS, INC., et al.,

Defendants.

Defendants' motion for an order dismissing the second amended complaint came on for hearing before this court on April 18, 2012. Plaintiff appeared by lead plaintiff's counsel David Bower, and defendants appeared by their counsel Michael Charlson and Benjamin Diggs. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS the motion.

BACKGROUND

This is a securities fraud case, filed as a proposed class action. Defendants are VIVUS, Inc., a pharmaceutical company ("VIVUS" or "the company"); Leland F. Wilson ("Wilson"), the CEO of VIVUS, and also a director of the company; and Wesley W. Day, Ph.D. ("Day"), the Vice President of Clinical Development of VIVUS. The members of the proposed class are "all persons who purchased or otherwise acquired VIVUS securities during the class period," which is defined as the period between September 9, 2009, and July 15, 2010.

At the time plaintiff filed the present action, VIVUS' lead product in clinical

development was Qnexa, an experimental drug for the treatment of obesity. Qnexa combines two ingredients previously approved by the U.S. Food and Drug Administration (“FDA”) – phentermine (approved in 1959 for short-term treatment of obesity), and topiramate (approved for prevention of seizures in 1996 and migraine headaches in 2004). Both phentermine and topiramate have some history of negative side effects, but both also have a well-documented safety profile, developed through use on millions of patients.

Under the Federal Food Drug and Cosmetic Act (“FDCA”), Pub.L. No. 75–717, ch. 675, 52 Stat. 1040 (1938), codified as amended at 21 U.S.C. § 301 et seq., a company seeking approval to market a drug must test the drug in the laboratory, and then submit an Investigational New Drug (“IND”) Application asking the FDA to approve clinical trials using human subjects. See 21 C.F.R. § 312, et seq. If the IND Application is approved, the company must complete three phases of clinical trials to determine the drug’s dosing, assess its efficacy, and monitor its safety. See 21 C.F.R. § 312.21. Upon successful completion of the clinical studies, the company submits a New Drug Application (“NDA”) seeking FDA approval to market the drug. 21 U.S.C. § 355(a).

Within 60 days of receipt of the NDA, the FDA makes “a threshold determination that the application is sufficiently complete to permit a substantive review.” 21 C.F.R. § 314.101. During the review, the FDA evaluates the NDA and then sends either an approval letter or a “complete response letter” asking for more information. 21 C.F.R. § 314.100. The FDA uses “its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards.” 21 C.F.R. § 314.105. The FDA may convene an “advisory committee” of doctors and other scientists to consider whether a drug’s health benefits outweigh its known risks, and issue a recommendation to the FDA. See 21 CFR §§ 14.160, 14.171.¹

As of the beginning of the class period – September 9, 2009 – VIVUS had

¹ Here, there was such an advisory committee – the FDA Endocrinologic and Metabolic Advisory Committee (referred to herein as the “Advisory Committee”).

1 completed certain Phase III clinical trials of Qnexa. The trials involved more than 4500
2 overweight and obese adult patients, and included a six-month trial known as EQUATE,
3 and two year-long trials known as EQUIP and CONQUER. Each of these trials was a
4 randomized, double-blind, placebo-controlled study, and included two of three Qnexa dose
5 levels (full-dose, mid-dose, low dose). Two of the trials were completed under a Special
6 Protocol Assessment ("SPA") from the FDA, indicating that the design, clinical endpoints,
7 and proposed analyses were acceptable for FDA approval.

8 On September 9, 2009, VIVUS released its top-line Phase III trial results, and issued
9 a press release announcing key results of its EQUIP and CONQUER trials: that obese
10 patients on Qnexa had achieved an average weight loss of 14.7% for study completers at
11 the top dose; that the results exceeded FDA efficiency benchmarks for obesity treatment;
12 and that Qnexa had demonstrated a favorable safety profile.

13 In December 2009, VIVUS submitted an NDA supported by these clinical trial
14 results, seeking to have Qnexa approved as an obesity drug. On March 1, 2010, the FDA
15 accepted the NDA and agreed to review Qnexa. Thereafter, the FDA evaluated the NDA,
16 and convened a meeting of the Advisory Committee.

17 As detailed in the second amended complaint, between the release of the initial
18 Phase III trial results on September 9, 2009 and late June 2010, VIVUS made a number of
19 public statements through press releases, conference calls, presentations, and SEC filings
20 regarding trial results, VIVUS' partnership opportunities, and Qnexa's prospects for FDA
21 approval and marketability.

22 In each of the press releases and conference calls, VIVUS underscored the risks
23 inherent in investing in developmental drugs such as Qnexa. As an example, the
24 September 9, 2009 press release identified "risks related to the development of innovative
25 products; and risks related to failure to obtain FDA clearances or approvals[.]" adding that
26 "[a]s with any pharmaceutical under development, there are significant risks in the
27 development, regulatory approval and commercialization of new products[.]" and "[t]here
28 are no guarantees that . . . any product will receive regulatory approval for any indication or

1 prove to be commercially successful.” The press release recommended that investors read
2 “the risk factors set forth in VIVUS Form 10-K for the year ended December 31, 2008, and
3 periodic reports filed with the Securities and Exchange Commission.”

4 VIVUS listed extensive risk factors in its SEC filings. For example, the VIVUS Form
5 10-K for the year ended December 31, 2009 included 47 pages of risk factors relating to all
6 aspects of the company’s business. In a 17-page portion of that discussion, the Form 10-K
7 identified and analyzed “risks relating to our product development efforts,” which included
8 the risks that the FDA might find one of defendants’ investigational products – including
9 Qnexa – not safe and effective, or might find the data from clinical trials insufficient to
10 support approval, or might require additional clinical studies. These risks and all their
11 potential ramifications were spelled out in considerable detail in the Form 10-K.

12 On July 13, 2010, two days before the date set for the Advisory Committee meeting,
13 the FDA publicly released VIVUS’ “VI-0251 (Qnexa®) Advisory Committee Briefing
14 Document,” and the FDA’s own analysis of the Qnexa clinical trial data (dated June 17,
15 2010). Following this release, the price of VIVUS’ stock climbed 17%, its largest one-day
16 increase since VIVUS had released its top-line Phase III trial results on September 9, 2009.

17 On July 15, 2010, the Advisory Committee convened a public hearing where it heard
18 testimony from VIVUS representatives and an FDA staff reviewer regarding Qnexa’s
19 efficacy and safety. VIVUS presented testimony by medical experts who opined that the
20 clinical studies had shown Qnexa to be beneficial and effective, and that any observed side
21 effects should not preclude approval. There was no dispute regarding efficacy, but the
22 FDA staff presenter and some Committee members raised concerns about long-term
23 safety, which they felt could not be fully evaluated based on the data from trials conducted
24 over only one year.

25 Following the testimony and discussion, the Committee voted 10 to 6 against
26 recommending Qnexa’s approval at that time, based on an “overall risk-benefit
27 assessment.” A number of the Committee members indicated that the decision whether or
28 not to recommend approval was a difficult one, and many of the members that voted to

1 recommend approval emphasized that VIVUS should conduct further studies in order to
2 obtain longer-term data regarding certain health risks.

3 On October 28, 2010, six weeks after the close of the class period, the FDA officially
4 denied VIVUS' NDA for Qnexa, as recommended by the Advisory Committee on July 15,
5 2010. Following this announcement, there was a substantial drop in the price of VIVUS
6 stock. However, the FDA also asked VIVUS to resubmit the NDA, with additional data. On
7 November 2, 2010, plaintiff Merle Kovtun filed this lawsuit, alleging claims under the
8 Securities Exchange Act of 1934. On February 12, 2011, the court granted plaintiff John
9 Ingram's motion to be appointed lead plaintiff and for approval of his choice of counsel.

10 In the fall of 2011, VIVUS resubmitted the NDA, with a second year of trial data. On
11 February 22, 2012, another FDA Advisory Committee convened, and voted 20-2 in favor of
12 recommending approval, so long as VIVUS conducted a postmarketing study to clarify the
13 cardiovascular risks. The Committee found the second year's data to be "consistent with
14 the safety profile" that VIVUS had reported in its original NDA. Following a further risk
15 evaluation, Qnexa was finally approved by the FDA on July 17, 2012, and is now being
16 marketed under the name Qsymia™.

17 On October 13, 2011, the court granted defendants' motion to dismiss the first
18 amended complaint. Plaintiff filed a 182-page second amended complaint ("SAC") on
19 November 9, 2011, alleging violation of § 10(b) of the Securities Exchange Act, and Rule
20 10b-5 promulgated thereunder, against all defendants; and violation of § 20(a) and § 20(b)
21 of the Securities Exchange Act, against the individual defendants. Defendants now seek
22 an order dismissing the SAC, for failure to state a claim.

23 DISCUSSION

24 A. Legal Standards

25 1. Motions to dismiss for failure to state a claim

26 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests for the legal
27 sufficiency of the claims alleged in the complaint. Ileto v. Glock, Inc., 349 F.3d 1191,
28 1199-1200 (9th Cir. 2003). Review is limited to the contents of the complaint. Allarcom

1 Pay Television, Ltd. v. Gen. Instrument Corp., 69 F.3d 381, 385 (9th Cir. 1995). To survive
 2 a motion under Federal Rule of Civil Procedure 12(b)(6) to dismiss for failure to state a
 3 claim, a complaint generally must satisfy the only the pleading requirements of Federal
 4 Rule of Civil Procedure 8 by providing a “short and plain statement of the claim showing
 5 that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2).

6 The court must “accept all factual allegations in the complaint as true and construe
 7 the pleadings in the light most favorable to the nonmoving party.” Outdoor Media Group,
 8 Inc. v. City of Beaumont, 506 F.3d 895, 899-900 (9th Cir. 2007). However, legally
 9 conclusory statements, not supported by actual factual allegations, need not be accepted.
 10 Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009). The allegations in the complaint “must be
 11 enough to raise a right to relief above the speculative level.” Bell Atlantic Corp. v.
 12 Twombly, 550 U.S. 544, 555 (2007) (citations and quotations omitted).

13 A motion to dismiss should be granted if the complaint does not proffer enough facts
 14 to state a claim for relief that is plausible on its face. See id. at 558-59. A claim has facial
 15 plausibility when the plaintiff pleads factual content that allows the court to draw the
 16 reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556
 17 U.S. at 678 (citation omitted). “[W]here the well-pleaded facts do not permit the court to
 18 infer more than the mere possibility of misconduct, the complaint has alleged – but it has
 19 not ‘show[n]’ – ‘that the pleader is entitled to relief.’” Id. at 679. In the event dismissal is
 20 warranted, it is generally without prejudice, unless it is clear the complaint cannot be saved
 21 by any amendment. See In re Daou Sys., Inc., 411 F.3d 1006, 1013 (9th Cir. 2005).

22 Although the court generally may not consider material outside the pleadings when
 23 resolving a motion to dismiss for failure to state a claim, the court may consider matters
 24 that are properly the subject of judicial notice. Lee v. City of Los Angeles, 250 F.3d 668,
 25 688-89 (9th Cir. 2001); Mack v. South Bay Beer Distributors, Inc., 798 F.2d 1279, 1282 (9th
 26 Cir. 1986). Additionally, the court may consider exhibits attached to the complaint, see Hal
 27 Roach Studios, Inc. V. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555 n.19 (9th Cir.
 28 1989), as well as documents referenced extensively in the complaint and documents that

form the basis of a the plaintiff's claims. See No. 84 Employer-Teamster Joint Counsel Pension Tr. Fund v. America West Holding Corp., 320 F.3d 920, 925 n.2 (9th Cir. 2003).

Finally, in actions alleging fraud, "the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). Under Rule 9(b), falsity must be pled with specificity, including an account of the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." Swartz v. KPMG LLP, 476 F.3d 756, 764 (9th Cir. 2007) (citations omitted). The allegations "must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." Bly-Magee v. California, 236 F.3d 1014, 1019 (9th Cir. 2001) (citation and quotations omitted). In addition, the plaintiff must do more than simply allege the neutral facts necessary to identify the transaction; he must also explain why the disputed statement was untrue or misleading at the time it was made. Yourish v. California Amplifier, 191 F.3d 983, 992–93 (9th Cir. 1999).

2. Pleading claims under the Securities Exchange Act

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

SEC Rule 10b-5, promulgated under the authority of § 10(b), makes it unlawful for any person to use interstate commerce

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b–5.

1 To state a claim for securities fraud under § 10(b) and Rule 10b-5, a plaintiff must
2 plead a material misrepresentation or omission by the defendant; scienter; a connection
3 with the purchase or sale of a security; reliance; economic loss; and loss causation.
4 Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, 552 U.S. 148, 157 (2008); see also Dura
5 Pharms, Inc. v. Broudo, 544 U.S. 336, 341-42 (2005). At the pleading stage, a complaint
6 stating claims under § 10(b) and Rule 10b-5 must satisfy both Rule 9(b) and the
7 requirements of the Private Securities Litigation Reform Act ("PSLRA"). WPP Luxembourg
8 Gamma Three Sarl v. Spot Runner, Inc., 655 F.3d 1039, 1047 (9th Cir. 2011).

9 The Private Securities Litigation Reform Act ("PSLRA") was enacted by Congress in
10 1995 to establish uniform and stringent pleading requirements for securities fraud actions,
11 and to put an end to the practice of pleading "fraud by hindsight." In re Silicon Graphics,
12 Inc. Sec. Litig., 183 F.3d 970, 958 (9th Cir. 1999). The PSLRA heightened the pleading
13 requirements in private securities fraud litigation by requiring that the complaint plead both
14 falsity and scienter with particularity. In re Vantive Corp. Sec. Litig., 283 F.3d 1079, 1084
15 (9th Cir. 2002); see also Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th
16 Cir. 2009). If the complaint does not satisfy these pleading requirements, the court, upon
17 motion of the defendant, must dismiss the complaint. 15 U.S.C. § 78u-4(b)(3)(A).

18 Under § 20(a) of the Exchange Act, joint and several liability can be imposed on
19 persons who directly or indirectly control a violator of the securities laws. 15 U.S.C.
20 § 78t(a). Under § 20(b) of the Exchange Act, "[i]t shall be unlawful for any person, directly
21 or indirectly, to do any act or thing which it would be unlawful for such person to do under
22 the provisions of this chapter or any rule or regulation thereunder through or by means of
23 any other person." 15 U.S.C. § 78t(b).

24 A plaintiff alleging a claim that individual defendants are "controlling persons" of a
25 company must plead facts showing a primary violation under the Exchange Act, and must
26 also allege that the defendant exercised actual power or control over the primary violator.
27 America West, 320 F.3d at 945; see also Howard v. Everex Sys., Inc., 228 F.3d 1057, 1065
28 (9th Cir. 2000).

B. Defendants' Motion to Dismiss

In the second amended complaint, plaintiff alleges that during the class period, defendants repeatedly heralded Qnexa's safety profile and expressed the view that FDA approval of Qnexa was likely, but failed to disclose the serious risks revealed by the study data and the inadequacy of the clinical data. Plaintiff asserts that prior to the July 15, 2010 Committee vote, VIVUS investors were not aware of Qnexa's serious and life-threatening health risks, or the inadequacy of the clinical data, and it was only when Qnexa's previously undisclosed and misrepresented safety issues were publicly disclosed as part of the Committee's "explanation" of the data that the price of VIVUS securities "plummeted."

1. Falsity

Defendants argue the SAC does not adequately allege falsity as required by the PSLRA. They contend that the statements regarding the safety results of Qnexa's trials were accurate in the context of the known safety profile of Qnexa's profile drugs, and that defendants' risk disclosures undercut plaintiff's claims. They also assert that other statements challenged by plaintiff are not actionable to the extent they are statements of general optimism, or forward-looking statements protected by the PSLRA's safe harbor.

Under the PSLRA – whether alleging that a defendant “made an untrue statement of a material fact” or alleging that a defendant “omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading” – the complaint must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . [must] state with particularity all facts on which that belief is formed.” Gompper v. VISX, Inc., 298 F.3d 893, 895 (9th Cir. 2002) (quoting 15 U.S.C. § 78u-4(b)(1)).

A statement or omission is misleading in the securities fraud context “if it would give a reasonable investor the ‘impression of a state of affairs that differs in a material way from the one that actually exists.’” Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 985 (9th Cir. 2008) (quoting Brody v. Transitional Hosp. Corp., 280 F.3d 997, 1006 (9th Cir. 2002)).

1 However, “vague claims about what statements were false or misleading [and] how they
2 were false” are subject to dismissal. Falkowski v. Imation Corp., 309 F.3d 1123, 1133 (9th
3 Cir. 2002); see also Metzler Inv. GMBH v. Corinthian Colls., Inc., 540 F.3d 1049, 1070 (9th
4 Cir. 2008).

5 Plaintiff alleges that defendants’ statements about Qnexa’s prospects were false and
6 misleading when made because defendants omitted to reveal relevant information about
7 the product’s health risks, and misrepresented the likelihood that Qnexa would be
8 approved by the FDA. Plaintiff asserts that defendants made false and misleading
9 statements in four press releases, three investor conference calls, one press interview, four
10 filings with the U.S. Securities and Exchange Commission, and fifteen healthcare
11 investment conferences, as previously alleged in the FAC. Each of the statements alleged
12 to be false or misleading – generally relating either to the results of the clinical trials, or to
13 Qnexa’s prospects for FDA approval – is followed by a list of between two and twelve
14 reasons (drawn from a list of approximately 20 reasons) that each statement is alleged to
15 be false.

16 For example, plaintiff quotes various VIVUS statements regarding efficacy and
17 safety in the clinical trials – such as that the studies “have produced . . . not only
18 remarkable efficacy, but remarkable safety as well; that “we have found literally no issues
19 of concern at this point; that “there were no differences in either total serious adverse
20 effects or drug-related serious adverse events between Qnexa and placebo;” that Qnexa
21 had a good “safety/risk profile;” and that there was “nothing of concern from the side effect
22 standpoint” – and alleges that such statements were false or misleading.

23 Each of these statements is followed by a list of “reasons” that the statement was
24 false or misleading. Among other things, plaintiff asserts that the Phase III trials showed
25 “significant, potentially serious and life-threatening adverse effects of the type that scuttled
26 approval for other obesity drugs, including potential teratogenicity, increased suicidal
27 ideation, cognitive issues, decreased bicarb, tachycardia, and possible renal stones;” that
28 Qnexa was associated with an “increased incidence” of psychiatric adverse side effects;

1 that there was a doubling of the rate of depression in the top dose group; that patients
 2 taking Qnexa reported an increased heart rate; that there was “a potential for
 3 cardiovascular risks;” that patients taking Qnexa had a “4 times higher rate of cognitive
 4 impairment;” that “a greater proportion of individuals treated with Qnexa” reported an
 5 adverse side effect in the areas of “sleep disorders, anxiety, and depression;” that during
 6 the Phase I trial, “a depletion of potassium in patients was noticed;” and that “patients in the
 7 Phase I trial were provided with an increase in potassium to mask the potential
 8 cardiovascular effect.”²

9 However, nowhere does plaintiff point to a statement made by defendants regarding
 10 a specific Phase III trial result and explain exactly what in the trial data (or elsewhere)
 11 shows that the statement about the trial results was false at the time it was made. That is,
 12 plaintiff has failed to allege facts showing “why the difference between the earlier and later
 13 statements is not merely the difference between two permissible judgments, but rather the
 14 result of a falsehood.” Philco Investments, Ltd. v. Martin, 2011 WL 500694 at *8 (N.D. Cal.
 15 Feb. 9, 2011).

16 Nor does plaintiff claim that defendants ever represented that no participant in the
 17 Qnexa trials experienced adverse effects, or that defendants attempted to gloss over the
 18 well-known and well-documented possible side effects of either of Qnexa’s two component
 19 drugs (including the history of adverse effects experienced by some individuals who used
 20 “Fen-Phen”³). A plaintiff cannot rely on conclusory allegations, but must instead allege
 21 specific facts that show how these alleged health risks necessarily precluded FDA

22
 23 ² Notwithstanding the amendment, the SAC still leaves it to the court and to defendants
 24 to try to match up a list of “reasons” with a series of snippets alleged to have been false
 25 statements. A complaint does not plead fraud with specificity when it alleges only that the
 26 defendant said one thing whereas the true fact is the opposite. Unless a plaintiff can plead
 facts showing that an alleged fraudulent statement is inconsistent with contemporaneous
 statement or condition, he has not pled fraud. See In re Glenfed, Inc. Sec. Litig., 42 F.3d 1541,
 1553 n.11 (9th Cir. 1994).

27 ³ Fen-Phen was a product that combined fenfluramine – which had been approved in
 28 1973 for short-term treatment of obesity – and phentermine. Fen-Phen was used for weight
 loss in the 1990s, but the FDA requested that manufacturers withdraw it from the market in
 1997 because of indications that it caused pulmonary hypertension and valvular heart disease.

1 approval. See Ronconi v. Larkin, 253 F.3d 423, 434 (9th Cir. 2001).

2 Here, defendants' SEC filings discussed the Fen-Phen history in some detail, and
3 also prominently disclosed that each of Qnexa's two constituents has its own side effect
4 profile (including the adverse effects and side effects identified by plaintiff) included in its
5 current product label and prescribing information, which defendants anticipated would be
6 included on the label for Qnexa, assuming it was approved by the FDA. Thus, as
7 defendants stated in some of the allegedly misleading statements, the trial results
8 presented "no issues of concern at this point" and "no surprises."

9 Plaintiff acknowledges that the side-effect profiles of phentermine and topiramate
10 were well-known long before the commencement of the class period, but alleges in the
11 SAC that "certain drugs should not be combined and the combination of these drugs can
12 increase the risks and magnitude or the side effects found in the individual constituent
13 compounds or create new side effects not seen in the individual compounds." For this
14 point, plaintiff cites to a 1999 article in the Journal of the American Medical Association,
15 which appears to have no particular relevance to the question of Qnexa's safety.
16 Moreover, while plaintiff alleges that during the class period, defendants "were in
17 possession of information" indicating that Qnexa "suffered from [this] effect[.]" the SAC
18 points to nothing in the trial data confirming that phentermine and topiramate, when
19 combined, did in fact increase the risks of the two, taken separately.

20 In short, because the side-effect profiles of phentermine and topiramate were well-
21 known and understood by the FDA, by the Advisory Committee, and by the markets, the
22 defendants' statements regarding the Qnexa trials must be viewed in that context. Thus,
23 when defendants reported that the Qnexa trials showed "nothing unexpected," it was clear
24 that the baseline expectations were set by the component drugs, and that understanding is
25 repeatedly emphasized in the very statements that plaintiff challenges.

26 Plaintiff alleges that defendants failed to adequately disclose multiple "serious" and
27 even "life-threatening" risks posed by Qnexa, which assertedly included psychiatric-related
28 adverse effects (suicidal ideation and depression), cognitive-related adverse effects

1 (confusion, difficulty with concentration/attention/memory, speech problems),
2 cardiovascular adverse effects, teratogenicity (risk of birth defects in children born to
3 women who might be taking Qnexa), metabolic acidosis, and cardiovascular adverse
4 effects.

5 In response, defendants argue that their statements about trial results that related to
6 specific potential side effects were truthful. They claim that plaintiff has taken isolated
7 comments regarding the above-listed side effects or adverse events, and has removed
8 them from the context, and has also failed to identify anything in the clinical data that
9 contradicted the statements made by defendants.

10 The court finds that the SAC fails to allege facts showing that defendants'
11 statements regarding the safety data from the Qnexa trials were materially false or
12 misleading. With regard to psychiatric results, defendants disclosed data for moderate and
13 severe depression-related adverse events, as well as for depression-related study
14 discontinuations, and they also made specific disclosures in the 2009 Form 10-K to the
15 effect that the psychiatric side effects observed in Qnexa's components might negatively
16 impact Qnexa's approval chances. Moreover, the incidence of psychiatric events was not a
17 reason cited by the FDA in 2010 for its non-approval of Qnexa. Indeed, FDA Committee
18 members noted the "absence of a clear signal for suicide risk."

19 Similarly, the FDA did not cite cognitive results as a reason for the initial disapproval
20 of Qnexa. In addition, market analysts, the FDA reviewer, and Committee members all
21 noted that the observed cognitive effects were well-known side effects of topiramate.
22 Plaintiff has alleged no facts showing that any of defendants' public statements about
23 cognitive effects were false or misleading, particularly given the context of the body of
24 information that had long been publicly available regarding the side effects of Qnexa's
25 components.

26 Plaintiff's assertions regarding cardiovascular safety results turn on two issues that
27 received almost no mention in the Committee's discussion – the withdrawal of the drug
28 combination Fen-Phen from the market in 1997, and the depletion of potassium. The FDA

1 Memo disposed of the Fen-Phen issue by simply repeating its prior conclusion, reached
2 after extensive research, that the phentermine component of that product was not the
3 cause of Fen-Phen's cardiovascular side-effects. Nothing in the Advisory Committee
4 record suggests that the Fen-Phen issue influenced the Committee's vote in July 2010.
5 Moreover, VIVUS's risk disclosures throughout the class period disclosed the threat that
6 Fen-Phen and its history posed to possible approval of Qnexa.

7 Nor is the court persuaded by plaintiff's claim that the Committee's suggestion of the
8 need for further study of the cardiovascular side effects somehow shows that defendants'
9 statements regarding cardiovascular safety were false and misleading. Plaintiff alleges no
10 facts showing that Qnexa showed any adverse effects beyond those identified on the label
11 for phentermine, which has been prescribed for more than 50 years. In addition, VIVUS
12 had announced, in its Advisory Committee Briefing Document publicly issued two days
13 prior to the July 15, 2010 Committee meeting, that it planned a comprehensive outcomes
14 study of cardiovascular effects, with a five-year average treatment duration.

15 Plaintiff's assertions regarding potassium depletion – which is a well-known side
16 effect of topiramate – are neither supported nor linked to the Phase III trial data. Moreover,
17 while the Committee briefing documents included data on decreased potassium levels, the
18 members of the Committee did not cite concerns regarding potassium as a reason for
19 voting against recommending approval.

20 As for teratogenicity and metabolic acidosis results, the SAC alleges no statement
21 (let alone a false and misleading one) about teratogenicity, save defendants' repeated risk
22 disclosures explaining that pregnant women were ineligible for the Phase III trials and that
23 Qnexa would have a label warning against use by women who are or are considering
24 becoming pregnant. Nor does the SAC mention any statement regarding metabolic
25 acidosis, or regarding "C labels" or "X labels," and alleges no facts showing that defendants
26 said one thing publicly but believed something else about risk of fetal harm.

27 Moreover, it seems clear, from the allegations in the SAC and the judicially
28 noticeable documents, that the FDA publicly released briefing documents, with extensive

1 trial data and the FDA's analysis of potential safety issues, two days before the Advisory
2 Committee held the meeting at which it voted not to recommend approval. In response to
3 the release of this FDA data, the price of the stock went up, not down. There are no facts
4 pled showing that any new data came to light on July 15, 2010 – the day of the Committee
5 vote – or that defendants concealed some material facts from the public prior to the vote.
6 The only new thing that occurred on July 15, 2010 was that a majority of the Committee
7 members voted not to approve Qnexa, based on data that had already been publicly
8 released.

9 Moreover, it is important to note that while the vote against recommending approval
10 was 10-6, some of the Committee members did make positive comments, to the effect that
11 the data showed that Qnexa was reasonably safe and should be approved, and of those
12 who voted against recommending approval, some indicated it was simply because they did
13 not feel comfortable with only one year's worth of data, and believed the trials had not
14 lasted a sufficiently long time.

15 Finally, to the extent that plaintiff argues that the fact that the FDA eventually
16 approved Qnexa is irrelevant because such approval fell outside of the class period, the
17 court finds it of significance because it vitiates plaintiff's theory set forth in the opposition to
18 the present motion that defendants "knew, by the first day of the Class Period, of the
19 serious adverse side effects observed in" the Phase III trials, and that "those side effects
20 presented a real, immediate and known risk that Qnexa could not and would not be
21 approved by the FDA based on the existing safety data." See Pltf's Opp. at 4 (emphasis
22 added).

23 Defendants make two additional arguments in support of their motion to dismiss –
24 that a number of the statements challenged by plaintiff are not actionable because they are
25 statements of general optimism, or because they are forward-looking statements that are
26 protected by numerous risk disclosures.

27 First, defendants assert that statements of general optimism are not actionable as
28 fraud in securities actions. "Vague, generalized, and unspecific assertions' of corporate

1 optimism or statements of ‘mere puffing’ cannot state actionable material misstatements of
2 fact under federal securities laws.” In re Cornerstone Propane Partners, L.P. Sec. Litig.,
3 355 F.Supp.2d 1069, 1086 (N.D. Cal. 2005) (quoting Glen Holly Entm't v. Tektronix, Inc.,
4 352 F.3d 367, 379 (9th Cir. 2003)); see also In re Syntex Corp. Sec. Litig., 855 F. Supp.
5 1086, 1096 (N.D. Cal. 1994) (internal citation omitted).

6 “When valuing corporations, . . . investors do not rely on vague statements of
7 optimism like ‘good,’ ‘well-regarded,’ or other feel good monikers.” In re Cutera Sec. Litig.,
8 610 F.3d 1103, 1111 (9th Cir. 2010). Statements such as “so far we're getting really great
9 feedback,” “we are very pleased with our progress to date,” we’re projecting “excellent
10 results” have been held to be “mere puffery.” See Wozniak v. Align Tech., Inc., 2012 WL
11 368366, at *4-5 (N.D. Cal. Feb. 3, 2012); In re Cornerstone, 355 F.Supp.2d at 1087; see
12 also In re Copper Mountain Sec. Litig., 311 F.Supp.2d 857, 868-69 (N.D. Cal. 2004)
13 (“run-of-the-mill” statements such as “business remained strong” are not actionable under
14 § 10(b)). Thus, defendants assert, statements that Qnexa has an “excellent” or
15 “compelling” risk/benefit profile, or that FDA approval or commercial success is likely, are
16 not actionable as false or misleading statements because they are no more than
17 statements of general corporate optimism.

18 To the extent that plaintiff challenges statements in which defendants merely
19 expressed confidence in VIVUS’ eventual success with Qnexa, such as statements
20 referring to Qnexa’s “excellent” or “compelling” risk/benefit profile, or statements to the
21 effect that the trials had shown “remarkable” safety and efficacy, the court finds, under the
22 above authority, that such statements are simply vague assertions of corporate optimism
23 and therefore are not actionable under the federal securities laws.

24 Second, defendants contend that their comments about Qnexa’s prospects were
25 forward-looking statements that are protected under the PSLRA safe harbor or the
26 “bespeaks caution” doctrine. The PSLRA provides a safe harbor for forward-looking
27 statements that identified as such and are accompanied by “meaningful cautionary
28 statements identifying important factors that could cause actual results to differ materially

1 from those in the forward looking statement.” 15 U.S.C. § 78u–5(c)(1)(A)(i).⁴

2 A forward-looking statement is “any statement regarding (1) financial projections, (2)
3 plans and objectives of management for future operations, (3) future economic
4 performance, or (4) the assumptions ‘underlying or related to’ any of these issues.”
5 America West, 320 F.3d at 936 (citing 15 U.S.C. § 78u–5(i)). “[I]f a forward-looking
6 statement is identified as such and accompanied by meaningful cautionary statements,
7 then the state of mind of the individual making the statement is irrelevant, and the
8 statement is not actionable regardless of the plaintiff’s showing of scienter.” In re Cutera,
9 610 F.3d at 1112.

10 Defendants note that every VIVUS press release contained specific warnings about
11 the uncertainties of forward-looking statements, and additionally referred investors to
12 VIVUS’ SEC filings, which in turn were chock-full of risk factors, including page after page
13 devoted to the very risks that plaintiff claims were hidden – potential difficulties with FDA
14 approval, the side-effect profiles of Qnexa’s two component drugs, the possible resulting
15 labeling restrictions for Qnexa, the possibility that the FDA might require additional,
16 expensive trials, concerns regarding Qnexa’s association with Fen-Phen, and many more
17 hazards.

18 Similarly, a representative of VIVUS began each of the conference calls with a
19 notice that during the course of the conference call or health care presentation, VIVUS
20 might make projections or other forward-looking statements regarding future events,
21 including future clinical trials or regulatory actions relating to Qnexa, and that such
22 projections should be considered predictions and that the actual result might differ, based
23 on the risks disclosed.

24 Nevertheless, plaintiff asserts that there is no “safe harbor” for any of the allegedly

25
26 ⁴ The “bespeaks caution” doctrine, which was formulated by courts prior to the
27 enactment of the PSLRA, operates in a similar fashion. This doctrine “provides a mechanism
28 by which a court can rule as a matter of law . . . that defendants’ forward-looking
representations contained enough cautionary language or risk disclosure to protect the
defendant against claims of securities fraud.” Provenz v. Miller, 102 F.3d 1478, 1493 (9th
Cir.1996) (citation omitted).

1 false and misleading statements because the statements were not identified as “forward
2 looking” when made, and also to the extent that any of the statements were in fact forward-
3 looking, there were insufficient cautionary statements identifying things that could go
4 wrong, or the disclosures were not sufficiently specific or “meaningful,” and because in
5 many instances, the disclosures themselves were misleading because they failed to
6 disclose material facts needed to make the statements truthful.

7 For example, plaintiff asserts that the disclosures that the FDA might not approve
8 Qnexa and that VIVUS might have problems that could cause it to cancel clinical trials,
9 were “generic” and could be applied to any company, and were also misleading because
10 there was no mention of the potential health problems revealed by the Phase III trials.
11 Plaintiff also contends that this risk disclosure was “nullified” by defendants’ statements
12 during the class period that they were “very confident” that Qnexa would be approved by
13 the FDA and were “extremely confident” about the outcome. Plaintiff also cites unfavorable
14 comments made by members of the Advisory Committee during the July 15, 2010
15 Committee meeting.

16 Projections about the likelihood of FDA approval are forward-looking statements.
17 They are assumptions related to the company's plan for its product, and as such fall under
18 the PSLRA's safe harbor rule. Each VIVUS press release or other public statement cited
19 by plaintiff included warnings about the uncertainties of forward-looking statements, and
20 also referred investors to VIVUS’ SEC filings. Those filings, in turn, were replete with
21 discussion of risk factors, including potential difficulties with obtaining FDA clearances and
22 approval; the known side-effects of Qnexa’s two components, and the possibility of FDA-
23 required labeling restrictions; the risk that the FDA might require additional, expensive
24 trials; and concerns regarding Qnexa’s association with Fen-Phen.

25 It cannot be over-emphasized that plaintiff does not claim that defendants presented
26 false information to the FDA or affirmatively misrepresented the data resulting from the
27 clinical trials, or even that there was a way that defendants could have known whether the
28 FDA would or would not approve Qnexa. Although plaintiff argues in opposition to the

present motion that the claims asserted in this case do not turn on whether defendants could have predicted the safety of Qnexa or the likelihood of FDA approval, but rather on whether defendants made misstatements that a reasonable investor would have relied on in making a decision to invest, it is undeniable that one major theme that underlies plaintiff entire theory of the case is that defendants misled investors by saying they expected Qnexa to be approved by the FDA (or by failing to disclose that they did not anticipate approval). See, e.g., SAC ¶¶ 12, 57, 201, 250, 255; see also Pltf's Opp., at 2, 19 n.17, 24 n.23, 28-29.

In order to be actionable under the securities laws, "an omission must be misleading." Brody, 280 F.3d at 1006. "[I]n other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." Id. That is, the failure to disclose must render an existing statement of fact false or misleading. For defendants in this case to fail to qualify the statement that they anticipated FDA approval by adding details of the results of the clinical trial was not to create an impression of a state of affairs that differed from one that actually existed, since the FDA review process had not even commenced at the time that defendants optimistically asserted that they anticipated FDA approval in the future. "[T]he fact that a prediction proves to be wrong in hindsight does not render the statement untrue when made." In re Syntex Corp. Sec. Litig., 95 F.3d 922, 929 (9th Cir. 1996).

In the absence of any facts indicating that defendants made statements about the trial results that were false at the time they were made, the statement that defendants expected that the FDA would approve Qnexa can at most be considered a reflection of a bad guess about an event that had not yet occurred. To say that investors were defrauded by defendants' statements about what a third party (the FDA) was going to do in the future is simply not plausible. Even if what plaintiff is trying to allege is that in stating that they anticipated FDA approval, defendants were attempting to persuade investors into putting money into a company without real prospects, such a scenario is unsupported by any facts in the FAC, and is also highly implausible under the facts presented.

1 2. Materiality

2 Plaintiff asserts that defendants made statements that reasonable investors relied
3 on, and which were proven to be false when the “truth” was revealed. However, the “truth”
4 that plaintiff refers to is the announcement by the Committee on July 15, 2010 that it had
5 voted not to recommend approval, primarily because a majority of the Committee members
6 were uncomfortable with recommending approval based on a one-year trial. But that is not
7 a “truth” that contradicts prior statements made by defendants.

8 It is undisputed that the market rose two days prior to the July 15, 2010
9 announcement, when the FDA publicly released both VIVUS’ briefing document and its
10 own analysis of Qnexa’s clinical trial data. The reaction of the market to the release of this
11 information was that the price of VIVUS’ stock climbed 17% on July 13, 2010, its largest
12 one-day increase since VIVUS had released its top-line Phase III trial results on September
13 9, 2009. This suggests that it was not defendants’ “failure to disclose” that caused the
14 market to rise during the class period, and also suggests the claim that defendants
15 deliberately concealed material information with the intent to defraud the public is
16 implausible.

17 Plaintiff contends that the market’s reaction to the disclosure of the data and the
18 FDA’s rejection of the application corroborates the SAC’s allegation of material falsity.
19 Plaintiff believes that if the information about the potential health risks of Qnexa had not
20 been material to the decision to purchase VIVUS’ stock, the market would not have reacted
21 as it did the day after the FDA Committee announced its decision on July 15, 2010.
22 Plaintiff claims that the fact that the price of VIVUS’ stock dropped on July 16, 2010, from
23 \$12.11 to \$5.41, shows that investors needed the “expert guidance and comments” from
24 the FDA Committee in order to be able to “fully digest and comprehend the true meaning of
25 the voluminous safety data.”

26 According to plaintiff, it was only when the FDA Committee voted and released its
27 comments that the investing public was able to actually perceive defendants’ “campaign of
28 deception.” Plaintiff asserts that because the FDA briefing document was 555 pages long,

1 it required some time for investors to review it. However, the key safety data, including the
2 supposed “revelations” upon which plaintiff’s fraud claims depend, were summarized in the
3 first seven pages of the FDA memo. Thus, plaintiff’s assertion directly contradicts the
4 “efficient market” allegations in the SAC, which plaintiff concedes are necessary to support
5 invocation of the “fraud on the market” theory of reliance. See SAC ¶ 34.

6 The Court agrees with defendants that plaintiff has not pled sufficient facts to show
7 that defendants’ disclosures were materially misleading statements under the federal
8 securities laws. Plaintiff concedes that defendants made numerous statements throughout
9 the class period regarding the results of the clinical trials of Qnexa, including possible side
10 effects. Plaintiff’s objection is to the specificity and comprehensiveness of defendants’
11 disclosures. However, it is well established that “§ 10(b) and Rule 10b–5(b) do not create
12 an affirmative duty to disclose any and all material information.” Matrixx Initiatives, Inc. v.
13 Siracusan, 131 S.Ct. 1309, 1321 (2011). In general, companies have no duty to disclose
14 facts, and must do so only “when necessary ‘to make . . . statements made, in light of the
15 circumstances under which they were made, not misleading.’” Id. (quoting 17 C.F.R.
16 § 240.10b–5(b)).

17 In sum, plaintiff’s allegations fail to show that defendants’ public statements were
18 false or misleading when made. Nor has plaintiff alleged facts showing “a substantial
19 likelihood that the disclosure of an allegedly omitted fact “would have been viewed by the
20 reasonable investor as having significantly altered the ‘total mix’ of the information made
21 available.” TSC Indus. Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976).

22 3. Scierter

23 Defendants argue that the SAC fails to meet the heightened standard for pleading
24 the required state of mind for a claim under § 10(b) and Rule 10b-5. Under the PSLRA,
25 whether alleging that a defendant “made an untrue statement of material fact” or alleging
26 that a defendant “omitted to state a material fact,” the complaint must, with respect to each
27 alleged act or omission, “state with particularity facts giving rise to a strong inference that
28 the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). To allege

that the defendant acted with the required state of mind, the complaint must plead facts creating a strong inference that the defendants made false or misleading statements either intentionally or with deliberate recklessness. Zucco Partners, 552 F.3d at 991; see also In re Daou Sys., Inc., 411 F.3d at 1014-15.

In determining whether the facts as pled give rise to a strong inference of scienter, the court must take into account plausible opposing inferences. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 310 (2007). As the Supreme Court stated in Tellabs, a plaintiff sufficiently alleges scienter “only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Id. at 324. The inquiry “is inherently comparative.” Id. “A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference.” Zucco Partners, 552 F.3d at 991 (citing Tellabs, 551 U.S. at 324).

In addition, when evaluating the scienter element, the court should “conduct a dual inquiry.” Id. at 991-92. First, the court must determine “whether any of the plaintiff’s allegations, standing alone are sufficient to create a strong inference of scienter.” Id. at 992. Second, “if no individual allegations are sufficient,” the court should “conduct a ‘holistic’ review of the same allegations to determine whether the individual allegations combine to create a strong inference of intentional conduct or deliberate recklessness.” Id. If the allegations are insufficient to state a claim, a court should grant leave to amend, “unless it is clear that the complaint could not be saved by any amendment.” Id. at 989 (quoting Livid Holdings, Ltd. v. Solomon Smith Barney, Inc., 416 F.3d 940, 946 (9th Cir. 2005)).

In the SAC, plaintiff alleges that defendants’ scienter is shown by the fact that – as established by the information attributed to the Confidential Witnesses (“CWs”) – the individual defendants were involved in and knowledgeable about the “core operations” of the company, and also by the fact that defendants had a financial motive to engage in

1 fraud.

2 Defendants argue that the facts alleged are insufficient to create a strong inference
3 of scienter. They contend that the allegations based on information attributed to the CWs
4 add nothing; that defendant Wilson's stock sales, made pursuant to a 10b5-1 plan, cannot
5 support an inference of scienter, much less a strong inference; and plaintiff's other "motive
6 and opportunity" allegations fall short because such financial motives can be ascribed to
7 corporate executives generally.

8 It is true, as plaintiff argues, that allegations of statements made by confidential
9 witnesses may under some circumstances shed some light on scienter, and it is also true
10 that the Ninth Circuit has recognized that allegations relying on the "core operations"
11 inference and allegations regarding "motive" to defraud may be considered in the overall
12 PSLRA analysis. In this case, however, the court finds that plaintiff has not alleged facts
13 sufficient to give rise to a "strong inference" of scienter.

14 A complaint relying on statements from confidential witnesses must pass two
15 hurdles to satisfy the PSLRA pleading requirements – the confidential witnesses whose
16 statements are introduced to establish scienter must be described with sufficient
17 particularity to establish their reliability and personal knowledge, and the statements that
18 are reported by the confidential witnesses must themselves be indicative of scienter.
19 Zucco Partners, 552 F.3d at 995; In re Daou Sys., 411 F.3d at 1015-16.

20 Here, the SAC incorporates statements from six confidential witnesses. CW1 was
21 the "Senior Clinical Project Manager at VIVUS" from September 2008 until January 2010,
22 was hired by and directly reported to Day, and was "involved in Qnexa research and clinical
23 trials[;]" CW1, who reported to Day's wife, Dr. Yee, during the Phase I trial, "confirmed that
24 . . . Day helped design and monitored" the Phase I clinical trial for Qnexa. CW1 stated that
25 one "concern" was with Qnexa's clinical studies "regarding the cardiac signal," because of
26 the depletion of potassium in patients (one of the known side effects of topiramate); and
27 that "another issue of concern" was "the need to gather more long-term data on the safety
28 of patients who become pregnant while involved in the trials." He also stated that the

1 “problem” with the depletion of potassium was “masked” because patients in the Phase I
2 trials were provided with additional potassium.

3 CW2 was “a scientist at the Lakewood New Jersey location” from 2006 until 2008,
4 and stated that “senior management should have been receiving monthly reports on how
5 the Qnexa trials were progressing.” CW2 stated that he/she and “others at the company”
6 discussed the risk that the previously identified side effects of Fen-Phen (which included
7 phentermine) might also apply to Qnexa.

8 CW3 was “employed as a regional sales representative” from 2000 to 2008, and
9 stated that there were only 12 individuals employed in the sales force at that time. CW3
10 stated that all sales personnel received “verbal reports on the progress of the clinical trials
11 of Qnexa,” which were usually given by Wilson and Vice-President of U.S. Operations and
12 General Manager Guy P. Marsh. CW3 also stated that the company did not have enough
13 money to fund its costs of operation.

14 CW4 was “a regional sales representative in California” from “approximately” 2004
15 until October 2010, and stated that eight or nine people – including Wilson and Day –
16 “control everything that goes on” at VIVUS. CW4 also stated that the biggest concern of
17 “people at VIVUS” was the risk that the previously identified side effects of Fen-Phen might
18 also apply to Qnexa. CW4 also stated that VIVUS did not have sufficient resources to take
19 a product from development to production.

20 CW5 was “the New England Regional Sales Manager” from April 2008 until “around”
21 November 2010, and stated that Wilson and Day “went over the Qnexa data as it was
22 internally reported.” CW5 also stated that after the clinical trials were complete, the data
23 “was passed up to senior management.” He stated that Wilson, “as well as other
24 management, thought” that if Qnexa encountered any problems with approval, such
25 problems could be overcome because “it could be labeled differently.” CW5 also stated
26 that there were discussions about “having Qnexa approved with a black box label.” He/she
27 added that “everyone, including senior management, knew” that Qnexa “had the potential
28 for” suicidality and heart problems.

1 CW6 was “a former VIVUS regional sales representative covering the Mid-West
2 region who worked at VIVUS for six years, including the class period, and left the company
3 “sometime in 2009.” CW6 “confirmed that each product in the pipeline, including Qnexa,
4 was discussed at sales meetings.” CW6 also stated that there was “debate” by “company
5 scientists” regarding the cardiac problems associated with Fen-Phen. CW6 believed that if
6 VIVUS was unable to obtain approval for Qnexa, the company would go out of business.

7 Thus, three of the CWs were “sales representatives,” one was a “sales manager,”
8 one was a “scientist” at the manufacturing facility, and one was a “project manager.”
9 However, four of the six CWs – CW3, CW4, CW5, and CW6 – are not alleged to have had
10 any experience with the development of Qnexa or the clinical trials. Rather, their
11 connection to the company is that they were involved in sales. Since Qnexa had not at that
12 time been approved for sale by the FDA, those CWs were necessarily involved in sales of
13 some other drug marketed by VIVUS. Another witness – CW2 – is alleged to have been a
14 “scientist” in the New Jersey manufacturing facility, but to have left that employment before
15 the Qnexa Phase III trials had concluded. Only CW 1 is alleged to have had any
16 involvement in research or clinical trials for Qnexa.

17 More importantly, however, the allegations regarding the CWs provide no details of
18 any fact that contradicted defendants’ public statements about Qnexa, and do not explain
19 when such information was allegedly known or who knew it. Nor are there any allegations
20 showing that the CWs would have known anything about those critical points. It is thus
21 difficult to evaluate whether the CWs were in a position to have any information regarding
22 defendants’ knowledge of the supposed concealed health risks of Qnexa.

23 Most of the statements attributed to the CWs go either to the “core operations”
24 theory; or to the alleged “concern” within the company regarding Qnexa’s supposed health
25 risks – particularly with regard to the possibility that participants in the Qnexa clinical trials
26 might experience the same negative side effects as the individuals who had taken Phen-
27 Fen in the 1990s; or to the fact that the company was allegedly short of money. However,
28 apart from CW1, there is no allegation of interaction between the CWs and defendants, or

1 any detail explaining how these CWs would have been in a position to know what plaintiff
2 claims they knew about defendants' motives or knowledge.

3 For example, plaintiff claims that CW3 (a regional sales manager) said that all the
4 sales personnel received "verbal reports" on the clinical trials of Qnexa, and that Wilson
5 and Day "went over the Qnexa data" as it was "internally reported." However, plaintiff does
6 not say what contact a regional sales manager would have had with the company's CEO or
7 VP of Clinical Development, and how he would have known about Wilson and Day
8 reviewing the Qnexa data.

9 Other CWs are alleged to have participated in internal "debates" about various
10 aspects of the safety of Qnexa or the progress of the clinical trials, but there is nothing
11 ominous or even surprising about employees of a pharmaceutical company that is
12 developing a new drug engaging in discussions about safety issues. Moreover, nowhere
13 does plaintiff allege, for example, that a CW reported to upper management about a
14 particular result of a clinical trial – e.g., that Qnexa caused a specific physical effect during
15 the trial – and that upper management proposed (or agreed) to conceal this result from the
16 public, or in fact did conceal it.

17 The SAC does not allege any specific information via the CWs that contradict any
18 specific statement attributed to the defendants, and instead cites the CWs only to show
19 there were "concerns" or "discussions" about potential safety issues within the company.
20 Moreover almost none of the CWs links Wilson or Day to this "constant discussion" of
21 health issues.

22 With regard to the "core operations" theory, plaintiff alleges that Wilson and Day
23 were aware of "the truth" about Qnexa by reason of their professional backgrounds and
24 their roles at VIVUS. Plaintiff notes that VIVUS was a fairly small company, and that Day
25 served as Vice President of Clinical Development during the class period, and was
26 identified as the person most responsible for the Qnexa studies, and that Wilson served as
27 CEO and a director during the class period, and signed and certified SEC filings.

28 Plaintiff contends that by virtue of their involvement in the day-to-day operations of

1 the company, Day and Wilson knew that the Phase III trials had showed potentially serious
2 and life-threatening adverse effects of the type that had “scuttled approval” for other obesity
3 drugs, and thus knew that the statements regarding Qnexa’s safety profile were false and
4 misleading; and that they also had detailed knowledge of the FDA approval process, and
5 therefore knew that Qnexa would not be approved by the FDA.

6 Plaintiff alleges that certain problems with Qnexa were discussed internally, but were
7 not disclosed to investors. These problems involved the previously identified side-effects of
8 Qnexa’s two components – phentermine and topiramate – and the question whether Qnexa
9 might have the same adverse effects as “Fen-Phen;” or the same adverse effects as
10 topiramate, which (as VIVUS stated in its SEC filings during the class period) has been
11 associated with teratogenic risks and cognitive side effects. Plaintiff also alleges that Day
12 and Wilson were aware that topiramate can lower blood potassium, resulting in cardiac
13 irregularities, and that this knowledge is demonstrated by the fact that they “manipulated”
14 Qnexa Phase I clinical trials by potassium augmentation.

15 The “core operations” theory is used to impute to a company’s key officers
16 knowledge of “facts critical to a business’s ‘core operations’ or an important transaction.”
17 This inference can satisfy the PSLRA either where there are allegations about
18 management’s role in a company, or where the nature of the relevant fact is of such
19 prominence that it would be absurd to suggest that management was without knowledge of
20 the matter. See South Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 783-86 (9th Cir. 2008);
21 Berson, 527 F.3d at 987-89.

22 Under Tellabs, “core operations” allegations are considered as part of a holistic
23 review of all of the allegations in the complaint. South Ferry, 542 F.3d at 784. However,
24 the “core operations” inference standing alone will generally not support a strong inference
25 of scienter absent “additional detailed allegations about the defendants’ actual exposure to
26 information.” *Id.* at 784-85, see also id., at 785 n.3.

27 Here, plaintiff’s position is that Wilson and Day must have known about the alleged
28 fraud simply by virtue of their involvement in VIVUS’ day-to-day business. If, in fact,

1 plaintiff had alleged facts showing specific misrepresentations or material omissions on the
2 part of defendants, then this argument might be more persuasive. In the absence of
3 adequate allegations of falsity, however, it appears to be of minimal significance, and
4 certainly is not sufficient to create a strong inference of scienter. "Where defendants make
5 cheerful predictions that do not come to pass, plaintiffs may not argue, based only on
6 defendants' prominent positions in the company, that they ought to have known better.
7 Instead, the PSLRA requires 'particular allegations which strongly imply [d]efendant[s']
8 contemporaneous knowledge that the statement was false when made.'" Berson, 527 F.3d
9 at 989 (quoting In re Read-Rite Corp., 335 F.3d 843, 847 (9th Cir. 2003)).

10 With regard to the alleged motive to defraud, the SAC asserts that defendants had
11 financial incentives to mislead investors. VIVUS' Form 10-K for FY 2009 indicated that the
12 company would require additional funding to continue with the research on Qnexa, and
13 plaintiff alleges that the company needed to raise funds through the sale of shares of stock,
14 and also wanted to find other companies with which to jointly develop and build the market
15 for Qnexa. Plaintiff asserts that this desire to raise capital and to initiate partnering
16 discussions provided the impetus for defendants to deceive the public regarding Qnexa's
17 safety and prospects.

18 Plaintiff alleges that the individual defendants were also motivated by various
19 financial incentives. Plaintiff points to VIVUS' April 30, 2012 Proxy Statement, which states
20 that compensation and bonuses for the CEO were tied to the raising of financing, and to
21 the status and results of the clinical trial programs for Qnexa. In addition, the company's
22 Equity Incentive Plan provided for the granting or vesting of various stock awards subject to
23 attainment of certain performance goals.

24 Plaintiff asserts further that Wilson's sale of the majority of his VIVUS holdings on
25 the first day of the class period (the same day that VIVUS issued the first press release
26 regarding Qnexa's effectiveness and its safety profile), and further sale on May 18, 2010
27 (the same day another conference call was held in which the company reiterated its
28 positive projections for VIVUS' success) strongly suggest the existence of a pre-conceived

1 plan by Wilson to artificially inflate the price of VIVUS' shares.

2 The court finds that these allegations are not sufficient to create a strong inference
3 of scienter. First, the fact that a corporation is seeking to acquire capital through the sales
4 of shares of stock is not in itself indicative of a motive to defraud. See, e.g., Lipton v.
5 Pathogenesis Corp., 284 F.3d 1027, 1038 (9th Cir. 2002).

6 Second, "it is common for executive compensation, including stock options and
7 bonuses, to be based partly on the executive's success in achieving key corporate goals."
8 In re Rigel Pharms., Inc. Sec. Litig., ___ F.3d ___, 2012 WL 3858112 at *12 (9th Cir. Sept. 6,
9 2012). As in the Rigel Pharmaceuticals case, in view of the requirement in Tellab that the
10 court assess scienter holistically, and that it take into account plausible opposing
11 inferences, the court "cannot conclude that there is fraudulent intent merely because a
12 defendant's compensation was based in part on such successes." Rigel Pharms., 2012
13 WL 3858112 at *12 (citing Rubke v. Capitol Bancorp Ltd., 551 F.3d 1156, 1166 (9th Cir.
14 2009)).

15 As for stock sales, only "unusual" or "suspicious" stock sales by corporate insiders
16 may constitute circumstantial evidence of scienter. In re Silicon Graphics, 183 F.3d at 986,
17 1001; Lipton, 284 F.3d at 1036-37. To evaluate whether stock sales are suspicious, the
18 court should consider the amount and percentage of shares sold; the timing of the sales;
19 and whether the sales are consistent with prior trading history. Metzler, 540 F.3d at 1067;
20 Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1232 (9th Cir.
21 2004).

22 Here, the allegations concerning the individual defendants' stock sales during the
23 class period do not support a strong inference of scienter. First, Day is not alleged to have
24 sold any VIVUS stock during this period. Wilson is alleged to have sold 200,000 shares of
25 VIVUS stock on September 9, 2009 – the first day of the class period – and to have sold an
26 additional 50,000 shares on May 3, 2010.

27 However, documents publicly filed with the SEC show that prior to the
28 commencement of the class period, Wilson sold 50,000 shares on June 12, 2009, at

1 approximately \$6.00 a share, and 50,000 shares on July 22, 2009, at \$7.00 a share. Then,
2 on September 9, 2009, he sold 150,000 shares at approximately \$11.00 a share, and
3 50,000 shares at \$12.00 a share. Finally, on May 18, 2010, he sold another 50,000
4 shares, at \$13.000 a share.

5 In the FAC, plaintiff noted that prior to the class period, Wilson had made sales of
6 stock pursuant to a Rule 10b5-1 trading plan that had been adopted prior to the start of the
7 class period, but also asserted that the number of shares Wilson sold on the first day of the
8 class period constituted a greater number of shares than he had sold during the prior year.
9 Nevertheless, plaintiff does not mention the Rule 10b5-1 trading plan in the SAC, which is,
10 of course, the operative complaint.

11 Stock sales can imply knowledge of falsity only when they are “dramatically out of
12 line with prior trading practices at times calculated to maximize” personal benefit. In re
13 Silicon Graphics, 183 F.3d at 986. To the extent that Wilson’s sales were made pursuant
14 to a Rule 10b5-1 trading plan calling for an automatic sale when the shares hit a certain
15 price, they were non-discretionary. See Metzler, 540 F.3d at 1067 n.11; In re MannKind
16 Secs. Actions, 835 F.Supp. 2d 797, 814 (C.D. Cal. 2011).

17 In any event, however, given Wilson’s overall trading history as reflected in the SEC
18 documents, the class period sales were not “dramatically out of line” with Wilson’s prior
19 trading practices. He sold a total of 350,000 shares between June 12, 2009 and May 18,
20 2010 – 100,000 of which were sold prior to the class period, and 250,00 of which were sold
21 on two occasions during the class period.

22 “While it is true that motive can be a relevant consideration, and personal financial
23 gain may weigh heavily in favor of a scienter inference, . . . allegations must be considered
24 collectively; the significance that can be ascribed to an allegation of motive, or lack thereof,
25 depends on the entirety of the complaint.” Tellabs, 551 U.S. at 325. Indeed, Ninth Circuit
26 case law makes clear that such “motive and opportunity” evidence alone is insufficient to
27 establish scienter at the pleadings stage. Lipton, 284 F.3d at 1035, 1038; see
28 also Howard, 228 F.3d at 1065.

1 Finally, the SAC alleges that individual defendants were motivated to make false and
2 misleading statements in order to ensure that VIVUS achieved stated corporate goals, as
3 they stood to gain stock and other incentive awards based on the attainment of
4 performance goals.

5 However, while plaintiff alleges that both Wilson and Day received substantial option
6 awards in 2009, there are no allegations in the SAC that either defendant exercised any of
7 those options during the class period, or that Day sold any stock at all during the class
8 period. And while plaintiff does allege that Wilson sold stock during the class period, those
9 sales were not “suspicious” or out of line with past trading practices.

10 The inference of scienter must be “strong,” which means that “a reasonable person
11 would deem the inference of scienter cogent and at least as compelling as any opposing
12 inference one could draw from the facts alleged.” Tellabs, 551 U.S. at 324. That is, “[e]ven
13 if a set of allegations may create an inference of scienter greater than the sum of its parts,
14 it must still be at least as compelling as an alternative innocent explanation.” Zucco, 552
15 F.3d at 1006. Here, even taking all the allegations of scienter collectively, the court finds
16 that plaintiff has not adequately alleged that a “malicious inference is at least as compelling
17 as any opposing innocent inference.” Id. at 991.

18 3. Section 20 claims

19 Plaintiff alleges a claim under both § 20(a) and § 20(b) of the Act. Defendants
20 argue that there can be no § 20 claim in the absence of a primary violation under § 10(b) or
21 Rule 10b-5. See Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 (9th Cir. 2002).
22 Because no securities fraud claim has been stated, the § 20 claims are also subject to
23 dismissal.

24 CONCLUSION

25 In accordance with the foregoing, the court finds that the motion to dismiss the
26 second amended complaint must be GRANTED. The alleged misstatements, viewed in
27 light of all the facts pled and the facts that were in the public domain, do not suggest an
28 attempt to deceive the public.

VIVUS spent tens of millions of dollars on the Qnexa Phase III clinical trials, based on data obtained in earlier-phase trials, as part of an effort to demonstrate the safety and efficacy of Qnexa. With regard to efficacy (which is not disputed), the year-long Phase III clinical trials showed dramatic weight loss and improvements in weight-related co-morbidities to a degree far beyond the established thresholds. As for safety, the two drugs that comprise Qnexa have long been approved by the FDA and have been used at higher dosing levels by millions of patients. While the facts as pled indicate that some dose-related side effects were observed in the Phase III trials, plaintiff alleges no facts indicating that any issues were observed that were outside the labels for Qnexa's component drugs, or were more severe than expected from the components.

Against this backdrop, a "collective" view of plaintiff's allegations does not approach a cogent and compelling inference of scienter, and certainly not one that is more plausible than that defendants genuinely believed in the promise of Qnexa. The "omissions" that plaintiff has alleged do nothing to undercut defendants' optimism, or to explain why defendants would have engaged in the reprehensible conduct that plaintiff believes occurred.

Further, plaintiff's scienter allegations are based on assertions attributed to the CWs, but plaintiff fails to plead facts sufficient to show that those witnesses were in a position to know anything about defendants' motives and intent; and also on conclusory allegations about defendants' motives extrapolated from routine corporate objectives (to obtain capitalization through a public offering) and non-discretionary stock trades (Wilson's sales of stock pursuant to Rule 10b5-1 plan that was in effect six months before the beginning of the class period).

Moreover, even if the CW allegations and the other motive allegations could be viewed as sufficient to support an allegation of scienter, it remains plaintiff's burden to show a strong inference of scienter, which inference is both cogent and compelling, and as plausible as any non-culpable inference that defendants' optimism was honest. The court finds that plaintiff has not met that burden.

1 Because the court finds that further amendment would be futile, given that plaintiff
2 has already been given leave to amend, and based on the above discussion, the dismissal
3 is with prejudice.

4
5 **IT IS SO ORDERED.**

6 Dated: September 27, 2012



PHYLLIS J. HAMILTON
United States District Judge